

SENATE BILL 662

J2

EMERGENCY BILL

0lr2018
CF HB 1381

By: ~~Senator Klausmeier~~ Senators Klausmeier and Della, Della, and Jacobs

Introduced and read first time: February 5, 2010

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted with floor amendments

Read second time: March 10, 2010

CHAPTER _____

1 AN ACT concerning

2 ~~Prescription Drugs – Controlled Dangerous Substances – Certification of~~
3 ~~Information on Delivery~~
4 Pharmacies – Delivery of Controlled Dangerous Substances

5 FOR the purpose of ~~requiring deliverers of certain prescription drugs and the~~
6 ~~recipients of those drugs to endorse a certain form; requiring the form to certify~~
7 ~~certain information; requiring the submission of the form to the State Board of~~
8 ~~Pharmacy; requiring the Board to adopt certain regulations; and generally~~
9 ~~relating to the delivery of prescriptions drugs that are controlled dangerous~~
10 ~~substances to patients~~ requiring certain pharmacies to require an adult to sign
11 for the delivery of certain controlled dangerous substances to a residence;
12 requiring the State Board of Pharmacy to waive certain requirements for
13 certain pharmacies under certain circumstances; making this Act an emergency
14 measure; and generally relating to pharmacies and the delivery of controlled
15 dangerous substances.

16 BY repealing and reenacting, with amendments,

17 Article – Health Occupations
18 Section 12-403 (b)(17) and (c)(3)
19 Annotated Code of Maryland
20 (2009 Replacement Volume)

21 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
22 MARYLAND, That the Laws of Maryland read as follows:

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Article – Health Occupations

2 12-403.

3 ~~(a) This section does not require a nonresident pharmacy to violate the laws~~
4 ~~or regulations of the state in which it is located.~~5 (b) Except as otherwise provided in this section, a pharmacy for which a
6 pharmacy permit has been issued under this title:7 ~~(1) Shall be operated in compliance with the law and with the rules~~
8 ~~and regulations of the Board;~~9 ~~(2) Shall be located and equipped so that the pharmacy may be~~
10 ~~operated without endangering the public health or safety;~~11 ~~(3) Shall ensure that a licensed pharmacist be immediately available~~
12 ~~on the premises to provide pharmacy services at all times the pharmacy is in~~
13 ~~operation;~~14 ~~(4) Shall be supervised by a licensed pharmacist who is responsible for~~
15 ~~the operations of the pharmacy at all times the pharmacy is in operation;~~16 ~~(5) Shall provide complete pharmaceutical service by preparing and~~
17 ~~dispensing all prescriptions that reasonably may be expected of a pharmacist;~~18 ~~(6) Shall provide services to the general public and may not restrict or~~
19 ~~limit its services to any group of individuals unless granted a waiver from this~~
20 ~~requirement by the Board;~~21 ~~(7) May not offer pharmaceutical services under any term or condition~~
22 ~~that tends to interfere with or impair the free and complete exercise of professional~~
23 ~~pharmaceutical judgment or skill;~~24 ~~(8) May not make any agreement that denies a patient a free choice of~~
25 ~~pharmacist or pharmacy services;~~26 ~~(9) May not participate in any activity that is a ground for Board~~
27 ~~action against a licensed pharmacist under § 12-313 or a registered pharmacy~~
28 ~~technician under § 12-6B-09 of this title;~~29 ~~(10) (i) Shall maintain at all times a current reference library that~~
30 ~~is appropriate to meet the needs of:~~31 ~~1. The practice specialty of that pharmacy; and~~32 ~~2. The consumers the pharmacy serves; and~~

1 (ii) ~~Shall comply with any regulations adopted by the Board~~
2 ~~establishing the types of texts required to be included in the reference libraries in each~~
3 ~~of the various practice specialty pharmacies;~~

4 (11) (i) ~~Shall maintain at all times the minimum professional and~~
5 ~~technical equipment and sanitary appliances that are necessary in a pharmacy;~~

6 1. ~~To prepare and dispense prescriptions properly; and~~

7 2. ~~To otherwise operate a pharmacy; and~~

8 (ii) ~~Shall:~~

9 1. ~~Be equipped with the minimum equipment and~~
10 ~~appliances specified by the Board under this section; and~~

11 2. ~~Be kept in a clean and orderly manner;~~

12 (12) ~~Shall store all prescription or nonprescription drugs or devices~~
13 ~~properly and safely subject to the rules and regulations adopted by the Board;~~

14 (13) ~~Shall:~~

15 (i) ~~Make and keep on file for at least 5 years a record of each~~
16 ~~prescription prepared or dispensed in the pharmacy;~~

17 (ii) ~~Disclose the records and files maintained of prescriptions for~~
18 ~~drugs or devices that identify or may be readily associated with the identity of a~~
19 ~~patient only in accordance with the provisions of Title 4, Subtitle 3 of the Health~~
20 ~~General Article; and~~

21 (iii) ~~Keep additional records as required by the rules and~~
22 ~~regulations adopted by the Board;~~

23 (14) ~~Except as otherwise provided under federal law, shall establish~~
24 ~~and maintain mechanisms to ensure that all prescription drugs or devices used within~~
25 ~~institutions that provide acute, subacute, or long term care, or within their related~~
26 ~~corporate subsidiaries, but stored outside a pharmacy, are stored properly and safely,~~
27 ~~subject to rules and regulations adopted by the Board and policies established by the~~
28 ~~institution;~~

29 (15) ~~Shall provide such personnel, automation, and technology as are~~
30 ~~necessary to allow the licensed pharmacist employee sufficient time to utilize the~~
31 ~~pharmacist's knowledge and training and to perform competently the functions of a~~
32 ~~licensed pharmacist as required by law;~~

~~(16) Shall provide such personnel, automation, and technology as are necessary to allow the licensed pharmacist employee or registered pharmacy technician to comply with the labeling requirements specified in § 12-505 of this title;~~

(17) With regard to a prescription drug that is delivered in this State by the United States mail, a common carrier, or a delivery service and is not personally hand delivered directly to a patient or to the agent of the patient at the residence of the patient or at another location designated by the patient, shall:

(i) Provide a general written notice in each shipment of a prescription drug that alerts a consumer that, under certain circumstances, a medication's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; ~~and~~

(ii) Provide a specific written notice in each shipment of a prescription drug that provides a consumer with a toll-free or local consumer access telephone number accessible during regular hours of operation, which is designed to respond to consumer questions pertaining to medications; AND

(iii) REQUIRE AN ADULT TO SIGN FOR THE DELIVERY OF A PRESCRIPTION DRUG OR SUBSTANCE THAT IS LISTED IN SCHEDULE II AS A CONTROLLED DANGEROUS SUBSTANCE, AS DEFINED IN § 5-101 OF THE CRIMINAL LAW ARTICLE, TO A RESIDENCE;

~~(18) WITH REGARD TO A PRESCRIPTION DRUG THAT IS A CONTROLLED DANGEROUS SUBSTANCE, AS DEFINED UNDER § 5-101(F) OF THE CRIMINAL LAW ARTICLE, THAT IS DELIVERED IN THIS STATE BY ANY MEANS TO A PATIENT OR TO THE AGENT OF THE PATIENT AT THE RESIDENCE OF THE PATIENT OR AT ANOTHER LOCATION DESIGNATED BY THE PATIENT, SHALL:~~

~~(i) REQUIRE THAT THE DELIVERER AND THE PATIENT OR THE AGENT OF THE PATIENT ENDORSE A DELIVERY FORM THAT IS APPROVED BY THE BOARD THAT CERTIFIES THAT:~~

~~1. THE PERSON WHO RECEIVES THE DELIVERY CLAIMS TO BE AT LEAST 18 YEARS OLD, AND THE CLAIM IS SUPPORTED BY DOCUMENTARY PROOF;~~

~~2. THE DELIVERER EXAMINED THE PERSON'S DOCUMENTARY PROOF; AND~~

~~3. THE PERSON IS THE PATIENT OR THE AGENT OF THE PATIENT; AND~~

~~(ii) SUBMIT EACH DELIVERY FORM ENDORSED UNDER ITEM (i) OF THIS PARAGRAPH TO THE BOARD;~~

1 ~~[(18)] (19) (i) May maintain a record log of any prescription that is~~
2 ~~requested to be filled or refilled by a patient in accordance with the provisions of Title~~
3 ~~4, Subtitle 3 of the Health General Article;~~

4 ~~(ii) If the prescription record of a patient includes the patient's~~
5 ~~Social Security number, shall keep the Social Security number confidential;~~

6 ~~(iii) May not list in the record log the type of illness, disability, or~~
7 ~~condition that is the basis of any dispensing or distribution of a drug by a pharmacist,~~
8 ~~and~~

9 ~~(iv) May not list a patient's Social Security number, illness,~~
10 ~~disability, or condition, or the name and type of drug received in the record log if the~~
11 ~~log is available to other pharmacy customers;~~

12 ~~[(19)] (20) May not allow an unauthorized individual to represent that~~
13 ~~the individual is a pharmacist or registered pharmacy technician; and~~

14 ~~[(20)] (21) Shall provide information regarding the process for resolving~~
15 ~~incorrectly filled prescriptions in accordance with existing regulations by:~~

16 ~~(i) Posting a sign that is conspicuously positioned and readable~~
17 ~~by consumers at the point where prescription drugs are dispensed to consumers; or~~

18 ~~(ii) Including written information regarding the process with~~
19 ~~each prescription dispensed.~~

20 (c) ~~(1) The Board may waive any of the requirements of this section for~~
21 ~~the University of Maryland School of Pharmacy, for nuclear pharmacy and dental~~
22 ~~pharmacy experimental and teaching programs.~~

23 ~~(2) The Board may waive the requirements of subsection (b)(5) and (6)~~
24 ~~of this section for pharmacies that are engaged in pharmaceutical specialties which~~
25 ~~are recognized by the Board under rules and regulations adopted by the Board.~~

26 (3) The Board shall waive the requirements of subsection [(b)(20)]
27 ~~(B)(21) (B)(17)(III) AND (20)~~ of this section for a pharmacy SERVICING A NURSING
28 FACILITY OR owned and operated by a hospital, nursing facility, or clinic to which the
29 public does not have access to purchase pharmaceuticals on a retail basis.

30 ~~(d) A nonresident pharmacy shall hold a pharmacy permit issued by the~~
31 ~~Board.~~

32 ~~(e) (1) In order to obtain a pharmacy permit from the Board, a~~
33 ~~nonresident pharmacy shall:~~

- 1 (i) ~~Submit an application to the Board on the form that the~~
2 ~~Board requires;~~
- 3 (ii) ~~Pay to the Board an application fee set by the Board;~~
- 4 (iii) ~~Submit a copy of the most recent inspection report resulting~~
5 ~~from an inspection conducted by the regulatory or licensing agency of the state in~~
6 ~~which the nonresident pharmacy is located; and~~
- 7 (iv) ~~On the required permit application, identify the name and~~
8 ~~current address of an agent located in this State officially designated to accept service~~
9 ~~of process.~~
- 10 (2) ~~A nonresident pharmacy shall report a change in the name or~~
11 ~~address of the resident agent in writing to the Board 30 days prior to the change.~~
- 12 (f) ~~A nonresident pharmacy shall:~~
- 13 (1) ~~Comply with the laws of the state in which it is located;~~
- 14 (2) ~~On an annual basis and within 30 days after a change of office,~~
15 ~~corporate officer, or pharmacist, disclose to the Board the location, names, and titles of~~
16 ~~all principal corporate officers and all pharmacists who are dispensing prescriptions~~
17 ~~for drugs or devices to persons in this State;~~
- 18 (3) ~~Comply with all lawful directions and requests for information~~
19 ~~from the regulatory or licensing agency of the state in which it is located and all~~
20 ~~requests for information made by the Board pursuant to this section;~~
- 21 (4) ~~Maintain at all times a valid, unexpired permit to conduct a~~
22 ~~pharmacy in compliance with the laws of the state in which it is located;~~
- 23 (5) ~~Maintain its records of prescription drugs or devices dispensed to~~
24 ~~patients in this State so that the records are readily retrievable;~~
- 25 (6) ~~During its regular hours of operation, but not less than 6 days a~~
26 ~~week, and for a minimum of 40 hours per week, provide toll-free telephone service to~~
27 ~~facilitate communication between patients in this State and a pharmacist who has~~
28 ~~access to the patient's prescription records;~~
- 29 (7) ~~Disclose its toll-free telephone number on a label affixed to each~~
30 ~~container of drugs or devices;~~
- 31 (8) ~~Comply with the laws of this State relating to the confidentiality of~~
32 ~~prescription records if there are no laws relating to the confidentiality of prescription~~
33 ~~records in the state in which the nonresident pharmacy is located; and~~

1 ~~(9) Comply with the requirements of subsection (b)(17), (18), and~~
2 ~~[(20)] (21) of this section.~~

3 ~~(g) Subject to the hearing provisions of § 12-411 of this subtitle, if a~~
4 ~~pharmacy or a nonresident pharmacy is operated in violation of this section, the Board~~
5 ~~may suspend the applicable pharmacy permit until the pharmacy complies with this~~
6 ~~section.~~

7 ~~(H) THE BOARD SHALL ADOPT REGULATIONS TO CARRY OUT~~
8 ~~SUBSECTION (B)(18) OF THIS SECTION.~~

9 SECTION 2. AND BE IT FURTHER ENACTED, That this Act ~~shall take effect~~
10 ~~October 1, 2010~~ is an emergency measure, is necessary for the immediate preservation
11 of the public health or safety, has been passed by a yea and nay vote supported by
12 three-fifths of all the members elected to each of the two Houses of the General
13 Assembly, and shall take effect from the date it is enacted.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.